IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

In re: LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION	Master File No. 12-995-WHW-MCA
LOUISIANA WHOLESALE DRUG CO., INC., on behalf of itself and all others similarly situated, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS Defendants.	Case No. 2:12-CV-00995-WHW-MCA
KING DRUG COMPANY OF FLORENCE, INC., on behalf of itself and all others similarly situated, Plaintiff, v. SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS Defendants.	Case No. 2:12-CV-01607-WHW-MCA

DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF MOTION TO COMPEL DIRECT PURCHASER PLAINTIFFS TO PRODUCE SALES AND PRICING DATA

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INTRODUCTION

Defendants move to compel the Direct Purchaser Plaintiffs ("DPPs") to produce data and documents regarding their sales and pricing for the Lamictal products at issue in this lawsuit, as well as documents related to competition and substitution between Lamictal and generic Lamictal. This information is plainly relevant to the parties' claims and defenses. Among other things, this information is necessary so that the Defendants can explore: (1) the appropriate measure of damages, both given the phenomenon of generic bypass and in light of GSK's pricing strategy with respect to Lamictal; (2) the definition of the appropriate product market; and (3) whether this case should proceed as a class action.

Defendants cannot explore these topics in a meaningful way merely through their own sales and pricing data. As detailed below, given both the phenomenon of generic bypass (whereby, upon generic entry, large retail pharmacies typically bypass wholesalers and buy generic drugs directly from manufacturers) and the robust price competition between the brand and generic products upon generic entry, Defendants need the DPPs' sales and pricing data for both brand and generic versions of Lamictal to assess how the settlement agreement actually impacted the DPPs.

Despite the plain relevance of this information, the DPPs have flatly refused to produce it. The DPPs have claimed that except for documents related to cost-plus contracts, any information relating to their own sales, prices, or profits—so-called "downstream" discovery—is irrelevant as a matter of law and thus categorically exempt from discovery. But the DPPs overreach: as detailed below, the authorities they cite do not support such an extraordinary departure from the broad scope of Rule 26. The DPPs are wrong in contending that this information is immune from discovery, and they have made no showing that it would be burdensome for them to produce it. Defendants' motion to compel should be granted.

BACKGROUND

Defendants' Joint First Set of Requests for Production of Documents to All Direct Purchaser Plaintiffs (the "RFPs") included requests for three categories of documents regarding the DPPs' sales and pricing of Lamictal products:

1. **Sales Data:** Data concerning the DPPs' sales and pricing of Lamictal and Generic Lamictal, including the impact that the entry of Generic Lamictal had on the DPPs' sales and revenues (RFPs Nos. 4-7, 11, 15).

2. **Contracts and Agreements:** Contracts and other related documents between the DPPs and their customers regarding the prices and other terms and conditions at which the DPPs sold (or their customers paid) for Lamictal or Generic Lamictal (RFP Nos. 9, 13).

3. **Pricing Strategy Documents:** Documents related to competition and substitution between Lamictal and Generic Lamictal, as well as other documents related to the DPPs' determination of prices for Lamictal or Generic Lamictal (RFP Nos. 7-8, 10).

The DPPs have categorically refused to produce any "documents or information related to Direct Purchaser Plaintiffs' own sales, prices or profits":

> Direct Purchaser Plaintiffs object to the Requests to the extent they seek documents or information related to Direct Purchaser Plaintiffs' own sales, prices or profits—often referred to as "downstream" discovery—because such discovery is irrelevant as a matter of law and contrary to controlling Third Circuit precedent, *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 220-21 (3d Cir. 2012), which applied the principles established by the Supreme Court in *Hanover Shoe v. United Shoe Machinery Corp.*, 392 U.S. 481 (1968) and *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). Under these controlling cases, a direct purchaser—such as the Direct Purchaser Plaintiffs here—is entitled to recover the "full amount" of an overcharge, and inquiry into the "downstream" effects of the overcharge—including, for example, inquiry into the direct purchaser's own prices, sales, and profits—is irrelevant as a matter of law. Following these fundamental principles, numerous courts, including district courts within the Third Circuit, have rejected attempts by antitrust defendants to take "downstream" discovery from direct purchasers. Accordingly, Direct Purchaser Plaintiffs object to the Requests insofar as they seek "downstream" discovery, as such Requests are not relevant. Direct Purchaser Plaintiffs also object to Requests seeking "downstream" discovery because the collection and production of the requested information is more burdensome and expensive than beneficial and is not proportional to the needs of the case. Direct Purchaser Plaintiffs will not provide documents or information concerning "downstream" discovery in response to the Requests.

(Jan. 8, 2016 Direct Purchaser Plaintiffs' Objections and Responses to Defendants' Joint First Set of Requests for Production of Documents ("RFP Responses"), attached as Ex. A, at 4 (General Objection J).) The DPPs incorporated this same objection in their responses to a number of Defendants' individual RFPs. (*E.g.*, Ex. A, RFP Responses Nos. 4-11, 13, 15, 23-24, 35.)

After the DPPs served their responses and objections to Defendants' RFPs, the parties had several telephonic meet-and-confers and exchanged correspondence in an effort to resolve their various areas of disagreement. Throughout, the DPPs have consistently declined to move from their blanket refusal to produce any "downstream" discovery. (*See, e.g.*, DPPs' June 8, 2016 Letter to Teva and GSK, attached as Ex. B, at 2; DPPs' July 21, 2016 Letter to Teva and GSK, attached as Ex. C, at 1-2.) And aside from the blanket and conclusory assertion in the DPPs' RFP Responses that "collection and production of the requested information is more burdensome and expensive than beneficial and is not proportional to the needs of the case" (Ex. A, RFP Responses, at 4), the DPPs have never explained why it would be burdensome for them to collect the sales and pricing information that Defendants seek.

ARGUMENT

Rule 26(b) allows parties to "obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]"[1] Fed. R. Civ. P. 26(b)(1). The scope of relevance under Rule 26 is broad: "[i]nformation within this scope of discovery need not be admissible in evidence to be discoverable." *Id.*; *e.g.*, *Hoover v Besler*, 2015 WL 5854248, at *5 (D.N.J. Oct. 5, 2015) (Arpert, J.) ("It is well established that the

[1] Unless otherwise noted, all emphases have been added, and all alterations, citations, and internal quotation marks have been omitted.

scope of discovery in federal litigation is broad.").[2] And it is well settled that relevant discovery under Rule 26 "is not limited to the precise issues set out in the pleadings or to the merits of the case"; rather, information that "may be relevant to the general subject matter of the action" is discoverable. *See First Sealord Sur. v. Durkin & Devries Ins. Agency*, 918 F. Supp. 2d 362, 383 n.12 (E.D. Pa. 2013).

The DPPs' sales data and other pricing-related documents that Defendants seek are relevant to theories Defendants are entitled to explore regarding key issues in this case, including (1) the appropriate measure of damages, both given the phenomenon of generic bypass and in light of GSK's pricing strategy with respect to Lamictal, as detailed below, (2) the definition of the relevant product market, and (3) class certification. Any of these issues alone would provide enough reason to compel the DPPs to produce this information, and they certainly compel production when considered together.

Indeed, the DPPs' blanket refusal to produce sales and pricing information that is directly relevant to the claims and defenses at issue cannot be squared with the broad dictates of Rule 26. Moreover, the DPPs' assertion that the Supreme Court's decisions in *Hanover Shoe* and *Illinois Brick Co.* somehow support a categorical exemption from the traditional liberal rules of discovery is incorrect. To the contrary, "neither *Hanover Shoe* nor *Illinois Brick* holds that downstream data is irrelevant or non-discoverable . . . . Nor can it be said that any of the courts interpreting *Hanover Shoe* hold downstream data irrelevant as a general rule." *In re Urethane*

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[2] *See also, e.g., Grohs v. Yatauro*, 2015 WL 7760185, at *2 (D.N.J. Nov. 30, 2015) (Mannion, J.) ("The Federal Rules of Civil Procedure set forth a liberal policy for providing discovery."); *Natale v. Wal-Mart Stores, Inc.*, 2016 WL 3467715, at *1 (M.D. Pa. June 24, 2016) ("Federal Rule of Civil Procedure 26(b)(1) provides for a broad scope of discovery, recognizing that the mutual knowledge of all the relevant facts gathered by both parties is essential to proper litigation.").

Antitrust Litig., 237 F.R.D. 454, 462-63 (D. Kan. 2006). The information that Defendants seek is relevant and discoverable, and it ought to be produced.

I. The DPPs' Sales and Pricing Information Is Relevant to Their Damages Claims.

The DPPs' damages claims are founded on a hypothetical "but-for" world—absent the Teva-GSK settlement—in which a Teva-manufactured generic, less expensive version of Lamictal would have been available for purchase and resale sooner, and in which GSK would have launched its own, "authorized" generic to compete with Teva's generic lamotrigine product. And indeed, in their Complaint, the DPPs allege that the Teva-GSK settlement "caused illegal anticompetitive harm to the direct purchasers of Lamictal tablets and/or Teva's generic version of Lamictal tablets by causing them to pay higher, artificially-inflated prices for those products than they otherwise would have absent the conduct alleged herein." (Consolidated Am. Class Action Compl., Dkt. 55 ("Compl.") ¶ 28.) The DPPs claim that as a result of the Teva-GSK settlement, they and other purchasers "were injured and sustained damages in the form of overcharges for branded and generic forms of Lamictal Tablets[.]" (*Id.*; *see also id.* ¶ 29 (similarly claiming that the DPPs and other purchasers suffered "overcharge[]" damages when paying for "branded and generic forms of Lamictal Chewables").) Indeed, at a recent hearing, counsel for the DPPs confirmed that this is the theory the DPPs are pursuing. "[W]hat [wholesalers] really want to do," counsel explained, "is they want to keep their acquisition costs as low as possible, so they love when generics come. When they sell brands, they end up losing money per sale because they sell on a cost-minus basis. When a generic comes, whoo hoo, it's great because your acquisition price goes down, and they are able to sell it at a -- you know, at a net price." (Oct. 31, 2016 Hearing Tr. at 31:10-16.)

Given the DPPs' own theories, information concerning their sales and pricing of Lamictal is relevant for at least two purposes with regard to damages. In particular, Defendants are

entitled to determine to what extent, if at all, the DPPs were actually harmed by the settlement agreement given (1) the phenomenon of generic bypass (whereby, upon generic entry, large retail pharmacies typically bypass wholesalers and buy generic drugs directly from manufacturers), and (2) GSK's pricing strategy during Teva's exclusivity period, where GSK offered branded Lamictal tablets at substantially reduced prices.

A. Generic Bypass Directly Affects Whether the DPPs Were Harmed by the Settlement Agreement.

In this case, Defendants cannot accurately measure the potential overcharges that the DPPs allege without assessing the extent of "generic bypass"—a well-recognized phenomenon that is directly relevant not only to the extent of overcharge the DPPs experienced but also to the appropriate quantum of damages from a delay in generic competition. (Together with this brief, Defendants also submit an affidavit from Bruce E. Stangle, Ph.D., an economist with more than thirty years of experience with antitrust analysis, who describes this phenomenon and its effect on overcharges in more detail.)

In antitrust challenges to agreements between competitors that impact the price of goods, courts typically assess damages by looking at the experienced overcharge—*i.e.*, the differences between the actual prices of the good and what the prices would have been "but for" the challenged agreement. *See Howard Hess Dental Labs., Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 374 (3d Cir. 2005) (The overcharge is "the difference between the price paid for goods actually purchased and the price that would have been paid absent the illegal conduct."). In pharmaceutical cases involving allegations that brand and generic manufacturers improperly delayed generic entry, the supposed delay-related overcharge would be calculated by comparing:

(1) the actual price of the drug, typically measured as the per-unit price of the branded drug (as sold during the period of alleged delay), with

(2) the "but for" price of the drug, typically measured as the per-unit price of the generic product (as sold ***after*** the period of alleged delay ended). (Ex. D, Nov. 4, 2016 Aff. of Bruce E. Stangle, Ph.D. ("Stangle Aff.") ¶¶ 1-9.)

But there are differences in how retail pharmacies buy brand-name drugs versus generic drugs, and any alleged damages in cases such as this one must, at a minimum, account for those differences. (*Id.* ¶ 10.) As noted above, wholesalers (like the DPPs here) typically buy brand-name drugs from brand manufacturers and resell them to other entities in the supply chain (like hospitals and retail pharmacies). (*Id.* ¶ 11.) But the supply chain often operates differently when it comes to generic drugs. Often times, large retail pharmacies—like CVS, Walgreens, and Rite-Aid—***bypass*** wholesalers (like the DPPs here) and buy generic drugs directly from generic manufacturers. (*Id.*) Figure 1 below illustrates this distinction, referred to as generic bypass (*id.*):

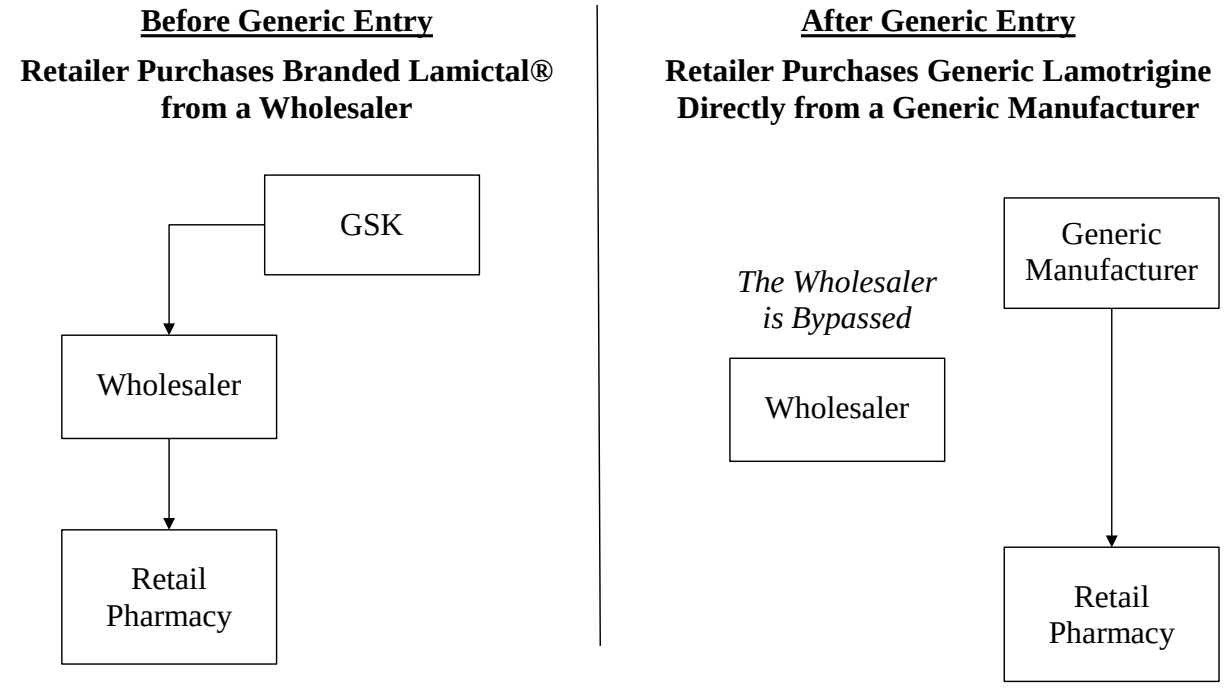

Figure 1

The left side of Figure 1 shows a stylized purchase of Lamictal before generic entry, with the product moving (a) from GSK, (b) to a wholesaler like the DPPs, and ultimately (c) to a retail pharmacy. (*Id.* ¶12.) The right side shows a stylized purchase of lamotrigine after generic entry, in which the product flows directly from a generic manufacturer (say, Teva or Dr. Reddy's) to a retail pharmacy. (*Id.*)

This generic bypass phenomenon has been widely recognized in pharmaceutical publications, antitrust case law, and academic literature (*see id.* ¶¶ 13-16, 21), and its relevance to the DPPs' damages claims is straightforward: a wholesaler cannot claim to have been harmed in buying a brand-name drug if, in the "but for" world with generic competition, that same wholesaler would ***not*** have bought ***any*** corresponding drug (brand-name or generic) at all. To put it differently, the DPPs cannot have suffered any damages for purchases of brand-name Lamictal that were subject to generic bypass, because in the "but for" world with an earlier market entry of generic Lamictal, the DPPs (and other purchasers) would not have bought ***bypassed*** Lamictal at ***any*** price, let alone a lower one. The DPPs cannot possibly recover damages for purchases they never would have made in the "but-for" world. *See, e.g.*, *Nat'l Farmers' Org., Inc. v. Associated Milk Producers, Inc.*, 850 F.2d 1286, 1306 (8th Cir. 1988) ("At base, an antitrust plaintiff's damages should reflect the difference between its performance in a hypothetical market free of all antitrust violations and its actual performance in the market infected by the anticompetitive conduct.").[3]

[3] Several district courts in other jurisdictions have held that direct purchasers can recover damages even with respect to bypassed units. *See In re Prograf Antitrust Litig.*, 2014 WL 7641156, at *4 (D. Mass. Dec. 23, 2014); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 2014 WL 2002887, at *6 (E.D. Tenn. May 15, 2014); *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 368-69 (D. Mass. 2004); *In re Niaspan Antitrust Litig.*, 2015 WL 4197590, at *1-2 (E.D. Pa. July 15, 2015). These decisions improperly conflate the two separate and distinct inquiries: (1) the extent to which there were any purchases that could give rise to damages in

The impact of generic bypass on the wholesaler's sales volume—and thus its impact on any potential alleged harm—is not merely theoretical. For example, one recent report estimated that "wholesalers retain only about 40% of the product volume once a product goes generic, because large self-warehousing customers no longer purchaser through the wholesale channel." (Stangle Aff. ¶ 15 (quoting Adam Fein, "2010-2011 Economic Report on Pharmaceutical Wholesalers," *Pembroke Consulting, Inc.*, June 2010, p. 39).) Another report discussing three major pharmaceutical wholesalers (AmerisourceBergen, McKesson, and Cardinal Health) similarly stated that "[m]ass retail pharmacies usually have sophisticated procurement operations and source most of their generic supply directly from manufacturers." (Stangle Aff. ¶ 14 (quoting Healthcare Observer, Morningstar, April 2014).) Rite Aid's annual reports filed with the SEC likewise indicated that before it changed its generic purchasing strategy in 2011, Rite Aid purchased "almost all of [its] generic pharmaceuticals directly from manufacturers." (Stangle Aff. ¶ 15 (citations omitted, alteration in original).) And in 2013, the rating agency Fitch reported that "most of the largest retail and mail-order pharmacies in the U.S. . . . source and distribute most generics and some specialty drugs on their own," and "often self-distribute generics in order to retain as much of the more favorable profit dynamics as possible." (*Id.* (citation omitted).) Thus, industry data indicates that wholesalers typically buy significantly fewer units after generic entry. (*Id.* ¶ 16.)

Data from other similar antitrust litigations further illustrate (and quantify) the point. By way of example:

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the first place, given the effect of generic bypass, and (2) the separate inquiry of whether purchasers passed on any of the harm they experienced to their customers (*i.e.*, the pass-on defense that *Hanover Shoe* forecloses).

- In an antitrust lawsuit involving the alleged delay of generic Skelaxin, the data showed that direct purchasers AmerisourceBergen, McKesson, and Cardinal Health together lost about 50-75 percent of their Skelaxin sales volume after generic entry, with Cardinal Health alone losing approximately 75 percent. (Stangle Aff. ¶ 17.)
- In litigation regarding the alleged delay of the proton pump inhibitor Nexium, the data showed that Cardinal Health and AmerisourceBergen's share of sales volume for another proton pump inhibitor (Prevacid) declined by about 95 percent after generic entry. (*Id.*)
- Economic experts in another litigation involving the drug Relafen estimated that after generic entry, sales volumes for Cardinal Health and McKesson fell 35.7% and 26.3%, respectively. (*Id.*)
- Data from litigation involving Paxil showed that after generic entry, "[t]he Big Three's combined share of purchases of the paroxetine molecule fell from 81% in the 20 months prior to generic entry to 36.6% post-generic entry." (*Id.*)
- In litigation involving Neurontin, economic experts estimated that generic bypass reduced damages to direct purchasers by approximately one-third. (*Id.*)

As these data points make plain, a wholesaler's brand purchase volume before generic entry is not an economically meaningful measure of volume on which to calculate damages, because in the but-for world, that wholesaler would not have replaced all of the brand volume it purchased in the real world with generic purchase volume instead. (*Id.* ¶ 18.)

To be sure, there are ways to account for the phenomenon of generic bypass in calculating damages. In particular, and as Dr. Stangle explains, one can use an estimate of the

brand purchase that would have been generic in the but-for world. (*Id.* ¶ 22.) That is, "to calculate damages to a drug wholesaler, it is necessary to model not only the price it would have paid in the but-for world, but also the volume of branded and generic products it would have purchased, including any drop in volumes created by generic bypass." (*Id.* (citation omitted).) But accounting for these changes in volume and costs (real world versus but-for world) is not enough. There are also differences—directly relevant to whether (and to what extent) the wholesaler was harmed—between the (higher) price at which the wholesaler ***resold*** the brand product in the real world, and the (lower) price at which it would have resold the generic product in the but-for world. (*Id.* ¶ 26.) These differences in resale prices must also be taken into account. (*Id.* ¶ 30.) As Dr. Stangle explains, "[i]f wholesaler plaintiffs are benefitting from the alleged delay,"—which Dr. Stangle's affidavit demonstrates is not only possible but probable—"then clearly the standard quantum of overcharge damages is highly inappropriate." (*Id.*) Any workable damages model must "measure only those damages attributable to" the challenged conduct at issue. *See Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013).

In this case, that means that accurate damages calculations can only be made if the DPPs produce their sales data pertaining to brand and generic versions of Lamictal, including units sold and the net sales dollars received. (*Id.*; *see also id.* ¶¶ 23-24, 26-29 & Figures 3 and 4 (providing stylized examples of damages calculations and explaining why damages calculations that take into account wholesalers' acquisition costs and sales data results are more accurate).) The DPPs sales data for brand and generic Lamictal is the most direct and reliable source that would allow Defendants to evaluate the impact that the settlement agreement had on the DPPs given the extent of generic bypass that each of the named DPPs actually experienced for this particular drug.

B. The DPPs' Pricing and Sales Information Is Also Relevant to Damages Given GSK's Competition Strategy During Teva's Exclusivity Period.

The DPPs' pricing and sales information is also relevant for another reason. The DPPs claim that under the settlement agreement, GSK agreed not to compete with Teva, which in turn induced Teva to delay its launch of generic lamotrigine tablets, and that the DPPs were harmed as a result. As explained in greater detail below, and contrary to the DPPs' allegations in this case, GSK competed with Teva during Teva's exclusivity period by offering ***branded*** Lamictal tablets at substantially reduced cost. Thus, Defendants are entitled to explore—including through downstream discovery—whether and how GSK's competition strategy affected the market and the quantum of damages, if any, the DPPs may be entitled to recover.

The DPPs' theory is that because the settlement agreement prevented GSK from competing with an authorized generic version of Lamictal during the terms of Teva's early entry licenses, Teva agreed to a later entry date than Teva would have agreed to absent the settlement, and less competition occurred in the actual world than would have occurred in a hypothetical but-for world. (*See* Compl., Dkt. 55 ¶¶ 18-19, 26-28.) But the DPPs ignore that GSK did, ***in fact***, compete with Teva during Teva's exclusivity period by offering branded Lamictal tablets at substantially reduced cost. Those discounts were given in one of two ways. In some cases, GSK would sell Lamictal to the wholesaler at full price, and the wholesaler would sell Lamictal to the retailer at the discounted GSK contract price plus a possible percentage mark-up, and then the wholesaler would "chargeback" GSK for the difference. In other instances, GSK would sell Lamictal to the wholesaler at full price, the wholesaler would sell Lamictal to the retailer at full price, and GSK would then pay a rebate to the retailer to provide the retailer with a discount. In both cases, because the sale transaction between GSK and the DPP did not reflect the price at which GSK sold Lamictal in the market, the transaction's market impact and true market price

can be determined only by looking at the full market transaction. Indeed, this competition calls into question both the characterization of the exclusivity provisions as "reverse payments," as well as their alleged impact on competition, or "antitrust injury," once generic entry did occur. *See Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (antitrust injury is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful"); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) (antitrust injury occurs only if the challenged conduct severely restricted competition in the relevant market).

In *FTC v. Actavis*, the Supreme Court instructed lower courts to evaluate reverse payment settlements agreements under the rule of reason by weighing their potential anticompetitive effects against their potential pro-competitive benefits. 133 S. Ct. 2223, 2237 (2013). Recently, Judge Goldberg of the Eastern District of Pennsylvania affirmed that downstream discovery is appropriate as litigants evaluate the competitive impact of challenged conduct. *See In re Suboxone Antitrust Litig.*, No. 13-md-2445, slip op. at 13-14 (June 27, 2016), attached as Ex. E hereto. There, the direct purchaser plaintiffs claimed that the defendants' actions had anticompetitive effects because they removed the only cost-efficient method for the generic to compete with the branded product. *Id.* at 7. The defendants sought downstream discovery to dispute those claimed anticompetitive effects by attempting to demonstrate that several other methods of competition—reflected in downstream sales—were available to the generic manufacturers. *Id.* Because measuring the effect of the challenged conduct on the market required an analysis of competition in the full market, including at the retail level, Judge Goldberg granted the defendant's motion to compel downstream discovery. Similarly, the DPPs here claim that GSK's agreement not to launch an authorized generic removed the only effective

method of competition with Teva's generic during its first days on the market. And as in *Suboxone*, Defendants dispute that alleged anticompetitive effect of the no-authorized generic agreement, by claiming that other methods of competition were available. Indeed, the fact that GSK actually competed here makes it all the more likely that competition could have occurred through other means. Thus, here too, measuring the effect of the challenged conduct on the market requires an analysis of competition in the full market, including at the retail level, and so Defendants' motion to compel downstream discovery should be granted.

The unique factual issues presented by GSK's competition also indicate it would be wholly inappropriate to evaluate the DPPs' damages by looking only to the amounts paid by the DPPs. While typically the overcharge that a direct purchaser suffers is assumed to serve as an adequate proxy for the market injury caused by the challenged conduct, *see Illinois Brick Co.*, 431 U.S. at 737, that cannot be said in this case for the reasons outlined above. And indeed, although the Third Circuit has held that overcharge damages are "the standard method" for measuring the quantum of harm, it has nonetheless recognized that "[a] court might potentially use a lost profits measure of damages." *Howard Hess Dental Labs.*, 424 F.3d at 374-75. Here, where the alleged overcharge to the DPPs cannot be said to approximate the harm to the market—and indeed likely overstates that harm, if any—Defendants are entitled to explore whether measuring the actual impact of the exclusive license agreement (which the DPPs claim constituted the illegal "reverse payment" in this case) on the DPPs would be a more appropriate measure of damages in this case.[4]

[4] While Defendants anticipate that the DPPs will come forth with a litany of purported reasons as to why it would not be appropriate to calculate damages by looking at the harm the DPPs experienced, under Rule 26, this Court need not decide the propriety of such a model now—and indeed it would be premature to do so in the absence of a fully developed record that includes downstream discovery.

But of course, unless Defendants know to which retailers the DPPs sold Lamictal tablets and at what price, Defendants cannot measure the exclusive license provision's full impact on the DPPs. In the same vein, unless Defendants are able to establish a baseline of the DPPs' experience in the market during a time when GSK did not implement its competition strategy, Defendants will be ill-equipped to determine how GSK's strategy impacted the DPPs because Defendants will have no information with which to make an accurate comparison. In short, because any difference in price the DPPs experienced in the actual world as compared to the but-for world is unlikely to be an adequate proxy of market impact, Defendants are entitled to the downstream discovery they seek to build a model that accurately reflects whether and to what extent the DPPs were harmed by the challenged provisions in the settlement agreement.

II. The DPPs' Sales and Pricing Information Is Relevant to the Market Definition.

To prevail on their Sherman Act claims, the DPPs must prove (among other things) that Defendants had monopoly power or restrained trade in a relevant product market. *See, e.g.*, *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). The DPPs have alleged two narrow product markets: (1) "Lamictal Tablets (in all its forms and dosage strengths), and AB-rated equivalent lamotrigine tablets"; and (2) "Lamictal Chewables (in all its forms and dosage strengths), and AB-rated equivalent lamotrigine chewable products." (Compl., Dkt. 55 ¶¶ 101, 105.) In other words, the DPPs have defined a product market by drawing a circle around Lamictal tablets and chewables along with their AB-rated generic equivalents, while excluding other drugs that treat epilepsy and bipolar disorder—two medical conditions for which Lamictal is indicated.

Neither Defendants nor this Court are required to accept the DPPs' bald product market allegations at face value. Rather, "proper market definition can be determined only after a factual inquiry into the commercial realities faced by consumers." *Queen City Pizza, Inc. v.*

Domino's Pizza, Inc., 124 F.3d 430, 436 (3d Cir. 1997). This includes inquiring into "reasonable interchangeability" (*i.e.*, the degree to which "one product is roughly equivalent to another for the use to which it is put," after considering factors that may include "price, use, and qualities"). *Id.* at 437; *accord, e.g.*, *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 513, (3d Cir. 1998), *aff'd*, 251 F.3d 153 (3d Cir. 2000) ("The outer boundaries of a product market are determined by evaluating which products would be reasonably interchangeable by consumers for the same purpose.").

As courts consistently have recognized, "defining the relevant product market [is] a fact sensitive inquiry that is fully developed during discovery." *Korkala v. Allpro Imaging, Inc.*, 2009 WL 2496506, at *5 (D.N.J. Aug. 12, 2009) (Cavanaugh, J.); *TransWeb, LLC v. 3M Innovative Props. Co.*, 16 F. Supp. 3d 385, 408 n.29 (D.N.J. 2014) (Hochberg, J.), *aff'd*, 812 F.3d 1295 (Fed. Cir. 2016) ("Definition of the relevant market is a question of fact."). To that end, Defendants asked the DPPs to produce "[a]ll documents concerning the competition between or among" generic and brand-name Lamictal Tablets and Chewables, on the one hand, and "any other pharmaceutical product" on the other hand, "including but not limited to information, analyses, studies, projections, investigations, and/or reports concerning the actual, potential, expected, or projected sales of such products or substitution among them." (Ex. A, RFP Responses, at 14.) The DPPs appear to concede the relevance of such information, because they agreed to "produce responsive, non-privileged documents concerning competition and/or substitution between Lamictal and Generic Lamictal and other pharmaceutical products, to the extent such documents exist." (*Id.* at 14-15.) But the DPPs still objected to this Request "to the extent it seeks 'downstream' discovery[.]" (*Id.* at 14.)

The DPPs' refusal to produce responsive documents by falling back on their "downstream discovery" objection is improper. Defendants are entitled to discovery on the scope of the DPPs' proposed product market, which includes (among other things) documents describing how the DPPs select which particular epilepsy and bipolar disorder drugs to buy and resell, as well as documents regarding the pricing, competition, and demand for such drugs. Such documents will very likely shed light on "the commercial realities faced by consumers," as well as "reasonable interchangeability" between Lamictal or generic Lamictal with other drugs used to treat epilepsy or bipolar disorder, including the extent to which the DPPs themselves regard different drugs in this class as reasonable substitutes. *See Queen City Pizza, Inc.*, 124 F.3d at 437-38; *Brokerage Concepts, Inc.*, 140 F.3d at 513-14.

In re Wellbutrin XL, another antitrust lawsuit involving the alleged delay of generic entry, is directly on point here. 268 F.R.D. 539 (E.D. Pa. 2010), *appeal filed*, No. 15-3559 (3d Cir. Nov. 4, 2015). There, as here, "[t]he direct purchaser plaintiffs' complaint alleged a narrow product market, consisting of just Wellbutrin XL and its generic equivalents." *Id.* at 542. As Defendants do here, "GSK sought discovery relevant to showing that Wellbutrin and its generic equivalents compete in a broader product market"; and (again, as the DPPs do here) the direct purchaser plaintiffs in *Wellbutrin* "objected on the ground that documents pertaining to their sales and pricing . . . comprised impermissible 'downstream discovery.'" *Id.* The *Wellbutrin* court ordered plaintiffs to produce this information, however, finding that it did not need to decide whether such discovery was "downstream," and that it was in any event "crucial to the defendants' defenses concerning the relevant product market size[.]" *Id.* at 543. Thus, setting aside that "downstream" data is not categorically immune from discovery for the reasons

detailed above, the Court should also order the DPPs to produce that data because it is relevant to market definition, another key element in this case.

III. The Direct Purchaser Plaintiffs' Sales and Pricing Information Is Relevant to Class Certification.

Finally, the DPPs' sales and pricing information also is relevant to whether any of the DPPs actually benefited from the alleged delay in generic entry and/or GSK's price reduction strategy, in that those DPPs bought and resold more units of Lamictal and/or at a greater profit margin than they would have in the hypothetical "but for" world with earlier generic entry and/or an authorized generic. That is because such a benefit can present a fundamental conflict within the class, precluding class certification. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1190 (11th Cir. 2003). Defendants recognize that the Third Circuit ruled otherwise in *In re K-Dur*, but in disagreeing with the Eleventh Circuit, the Third Circuit also noted that "[t]he case law . . . reveals a split in authority." 686 F.3d at 223. Moreover, several Third Circuit cases decided since *K-Dur* cast real doubt on whether the same result would obtain if the court confronted the same issues today. For example, *Carrera v. Bayer Corp.*, 727 F.3d 300 (3d Cir. 2013), *pet. for reh'g denied*, 2014 WL 3887938 (3d Cir. May 2, 2014), held that class certification was not appropriate where unharmed class members could not be excluded from the class. 727 F.3d at 308-09 ("[A] class action cannot be certified in a way that . . . masks individual issues."). *Carrera*'s holding is in serious tension with *K-Dur*'s assessment that differences in how a settlement impacted class members do not matter at the class certification stage. Given the circuit split and shifting landscape in class action jurisprudence in the Third Circuit, ordering the DPPs to produce this disputed discovery will help develop a fulsome factual record to explore relevant class issues in a meaningful way.

IV. "Downstream" Documents Are Not Categorically Exempt from Discovery.

The DPPs contend that any "documents or information related to Direct Purchaser Plaintiffs' own sales, prices or profits" are purportedly "irrelevant as a matter of law" under *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *Hanover Shoe v. United Shoe Machinery Corp.*, 392 U.S. 481 (1967), and *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). (*See* Ex. A, RFP Responses, General Objection J, at 4.) Based on this case law, the DPPs' have taken the position that ***any*** information that in ***any*** way relates to their sales or pricing is categorically exempt from discovery. As Defendants have explained, this case is fundamentally different from all of the cases DPPs cite because of GSK's competition-enhancing strategy during Teva's exclusivity period. Even setting that fact aside, however, none of those cases support such an extraordinary departure from the broad scope of Rule 26.

In fact, neither *Hanover Shoe* nor *Illinois Brick* dealt with discovery at all. Rather, these Supreme Court decisions held on the merits that except in limited circumstances (like those presented here), "downstream" information cannot be used for the sole purpose of showing that a direct purchaser "passed on" an overcharge to its own customers (that is, indirect purchasers). But *Hanover Shoe* and *Illinois Brick* certainly did ***not*** impose a categorical ban on downstream discovery. Instead, "[t]he *general* rule gleaned from *Hanover Shoe* and its progeny is that downstream data cannot be used to support a pass-on defense; that is, the defense that the plaintiff has no damages when he passed the overcharge on down the production line. Nor can it be said that any of the courts interpreting *Hanover Shoe* hold downstream data irrelevant as a general rule." *In re Urethane*, 237 F.R.D. at 462-63 (emphasis added); *see also id.* at 463-64 (rejecting plaintiffs' argument that downstream discovery is categorically irrelevant where "Defendants [were] not seeking discovery of data in order to assert a pass-on defense").

The Third Circuit's decision in *In re K-Dur* is not to the contrary. That decision (like *Hanover Shoe* and *Illinois Brick*) was narrow and made specifically in the context of Rule 23's predominance requirement. The Third Circuit did ***not*** rule that any downstream discovery—no matter for what purpose—is irrelevant as a matter of law. As explained above, GSK's competition strategy distinguishes this case from all other reverse payment cases. Moreover, both the district court and the Third Circuit in *In re K-Dur* recognized that downstream sales and pricing information may "relate to the quantum of damages, rather than the fact of injury." *In re K-Dur Antitrust Litig.*, 2008 WL 2699390, at *15 (D.N.J. Apr. 14, 2008) (Orlofsky, J. (ret.)); *see also* 686 F.3d at 222 (quoting this language from the district court's decision and noting that "[t]o the extent that there were minor variations" in the timing of plaintiffs' purchases of the drug at issue, "they can be handled at trial in the context of damages."). Other courts have reached similar conclusions. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 56 (D. Mass. 2013)) ("the issue of generic bypass primarily affects the measure of damages"); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 297, 317 (E.D. Mich. 2001) (direct purchaser plaintiffs may not "ignore the effect of the . . . by-pass phenomenon on some wholesale class members" so that they "will not overstate the extent" of damages).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court enter an Order compelling the DPPs to produce the data and documents requested.

Dated: November 4, 2016

Respectfully submitted,

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